TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF:)
)
STAKEHOLDERS MEETINGS)
NATIONAL FOOD PROCESSORS)
ASSOCIATION MEETING)

Pages: 1 through 40

Place: College Park, Maryland

Date: February 25, 2004

HERITAGE REPORTING CORPORATION
Official Reporters
1220 L Street, N.W., Suite 600
Washington, D.C. 20005-4018
(202) 628-4888
hrc@concentric.net

IN THE UNITED STATES DEPARTMENT OF AGRICULTURE

IN THE MATTER OF:

STAKEHOLDERS MEETINGS)
NATIONAL FOOD PROCESSORS)
ASSOCIATION MEETING)

Room 1A-001
Federal Drug Administration
5100 Paint Branch Parkway
College Park, Maryland

Wednesday,
February 25, 2004

The parties met, pursuant to the notice, at 1:37 p.m.

BEFORE: MS. CINDY SMITH

APPEARANCES:

For United States Department of Agriculture, Animal Plant Health Inspection Service, Biotechnology Regulatory Services:

REBECCA BECH, Associate Deputy Administrator
SUSAN KOEHLER
JOHN TURNER
NEIL HOFFMAN

For National Food Processors Association:

JEFFREY T. BARACH, Ph.D., Vice President

P R O C E E D I N G S

(1:37 p.m.)

MS. SMITH: Welcome to our stakeholder discussion series on our upcoming environmental impact statement, or EIS, and our revised plant biotech regulation.

We want to thank you for taking time from your busy schedule to join us for this meeting and share your thoughts with us today.

The purpose of these meetings is twofold. First, for us to share information regarding our plans to move forward on our environmental impact statement, as well as our new regs. And secondly, to gather diverse and informative input which will support thoughtful and effective decision-making on our part in the development of our new regulations.

We have here from BRS most of our management team, as well as several staff members, and where available, other key agency personnel that support BRS will be joining us in these meetings, as well.

I should also mention two key individuals who have been dedicated to providing full-time management of our work to complete both the environmental impact statement and our revised regulations. John Turner, who you likely know, is a very important member of our leadership team here in BRS. And I'm very pleased to say that John is leading this

effort.

And a second individual, which is a new face you may not be familiar with, Dr. Michael Wach, a recent BRS hire as an environmental protection specialist within our Environmental and Ecological Analysis Unit. In addition to possessing both a Ph.D. and an environmental J.D. as well, Michael brings research experience in plant pathology and weed science, as well as legal experience working on cases involving NEPA, the Clean Water Act, the Clean Air Act, and other environmental laws.

With that short introduction, I would like to turn it over to John Turner, who will be providing the additional background information before you share your information with us.

MR. TURNER: As you likely know, we recently participated in inter-agency discussions with FDA, EPA, and the White House, which, while concluding that the coordinated framework --

(Interruption.)

MR. TURNER: So while I concluded that the coordinated framework provides an appropriate science-based and risk-based regulatory approach for biotechnology, the Plant Protection Act of 2000 provides a unique opportunity for APHIS to revise its regulations, potentially expand our authority, while leveraging the experience gained through

our history of regulation to enhance our regulatory framework, and position us well for the future advancements of this technology.

We also have concluded those discussions with general agreement on how our biotech regulatory approach would evolve. Still, there is much opportunity for public and stakeholder input, as we move forward and develop the specifics of our regulatory enhancements.

Given this, what we would like to do in these meetings is to give an opportunity to hear your thoughts, as well as an informal give and take of ideas.

We have a unique opportunity for this type of discussion, since we're not yet in the formal rule-making phase of the process. So we're free to speak with open exchange of ideas with stakeholders and the public.

Our discussion will be professionally transcribed primarily for two reasons. First, an accurate record of our discussion will facilitate our ability to capture and refer to your input. And secondly, in the interest of transparency and fairness to all stakeholders, we will be making available as part of the public record, and potentially on our website, documentation of all the stakeholder discussions, so that the public and other stakeholders will have the benefit of each of the discussions that we will be conducting this week.

Of course I should emphasize that while we will be happy to share information on the direction we are likely to take during the process, that what we will be sharing is our thinking in BRS. And that during the process, public and stakeholder input will likely influence our thinking.

In addition, other officials at USDA, including our Administrator, the Undersecretary, our Office of General Counsel, and the Secretary can certainly be expected to provide insightful direction, as well.

So while we value all input, it is important to recognize that our thinking will likely evolve. So that we may have enthusiastic discussions today on a particular aspect of the revisions, it will be an evolving process.

Finally, since it will be hard to predict what the final regulations will look like, I would like to share with you some of the overall BRS priority areas of emphasis to set direction and help guide the development of the implementation of the regulatory and policy strategies and operations.

First is rigorous regulation, which thoroughly and appropriately evaluates and ensures safety, and is supported by strong compliance and enforcement.

Next is transparency of the regulatory process and regulatory decision-making to stakeholders and the public. This is critical to public confidence.

We want a science-based system, ensuring that the best science is used to support regulatory decision-making to assure safety.

Communication, coordination, collaboration with the full range of stakeholders is also important.

And finally, international leadership, ensuring that international biotech standards are science-based, supporting international regulatory capacity-building, and considering international implications of policy and regulatory decisions.

As we prepare to begin our discussions now, I want to let you know that for effective transcription of our session, that all statements and questions need to be directed into the microphone. And for those of you who have not previously identified yourselves, please do so for the transcriber, so you can do that one time as you start, and state your name prior to speaking.

With that, I will open up the floor to discussion, and I look forward to hearing your comments.

MR. BARACH: Thank you very much. I'm Jeff Barach with National Food Processors Association. Welcome to you all. I haven't gotten a chance to meet all of you, but it's quite a good group here.

As Cindy mentioned, when she started the concept of these meetings, she was talking about one-on-one, and I

guess I took her literally. We initially had quite a few folks who were interested, but they have sort of gone their own way and have set up their own meetings on individual bases with this group. So everybody that I had talked to, at least from our membership, got an opportunity, or will have an opportunity, to meet with this group and discuss the issues.

So I'm representing National Food Processors, which is the broadest part of our membership. Our membership includes about 80, 85 percent food processors, and about 15 percent suppliers. And within those supplier groups are some of the folks that you have perhaps talked to already. They supply materials or technology or whatever to the food industry. So companies that are producing the biotech events are actually members of NFPA, also. As you can imagine, some of our discussions get kind of lively at times with food processors and suppliers there in the same room.

But it is for a very good discussion at our meetings, and in relation to what the government is doing with regulations, I want to commend this group, and especially Cindy, in pulling this type of a discussion group together, because I think it really represents just the goals that you have. And as you stated earlier, John, about transparency and communication, I think it's a very good

step forward to it.

This helps me considerably, as I will probably be likely the one who puts the comments together to help formulate some of my thoughts as I start to draft out what we're going to say as a united body of the food chain. These comments often do come from specific members, but they do represent the entire segment of the food industry, which I think is beneficial to us to have one voice, and also beneficial to you to know where we're coming from on some of these issues.

As I said and have spoken in several different forums, the food processors are really kind of, are a stakeholder, or sort of a self-proclaimed stakeholder here. Because, as you can imagine, what's going on down on the lower end of the food chain with seeds and developments of research has an impact all the way up.

So early on, when PMPs became very visible a couple years ago, one of our goals was to make sure that we had a voice, and that we were looking at the development of, the parallel development of the technology, as well as the regulations, at the same time. So it was important for us to declare ourselves as a stakeholder, and I guess it's worked because we're here. So I appreciate that.

We have pretty simple goals in, when thinking about the development of regulations, how they're going to

evolve, protecting the food supply of course is one of our primary goals here. But also, we are looking at the development of biotechnology as a benefit, a current and future benefit for the food industry in total. So we want the development of the technology to proceed basically as it will. We want consumer acceptance to progress as it can. And the food industry in the meantime recognizes that there are some risks in the whole system, and we want to mitigate those risks.

So we are for biotech. We are for the advantages that it brings to the agricultural industry. We're looking with wide eyes at the future, thinking that there are going to be some consumer benefits to come out of the technology. We are very interested in those. Our membership and consumers in general will be interested in those manifests when they do occur. So that kind of has kept our strong interest and strong support on the table regarding biotech.

At the same time, I mentioned the risks associated with certain aspects of it, the pharmaceuticals. We have been very outspoken in the past couple years on that issue, because we see it as important to the integrity of the food supply.

So those are our goals. They are pretty straightforward. And as we put our comments together, that will come out pretty strong in where we are.

You know, we probably won't get down to some of the levels that many of the individuals that you've talked to and will talk to will. We just won't be at that level of actually the mechanics of what's going on. But we want to have discussion, in sort of a broad sense, of the impacts of biotech plants and plant-made pharmaceuticals.

These are very timely discussions that we're having, because as I understand, there is nothing commercially available, as far as a plant-made pharmaceutical, as yet, although there's -- and will continue to go on.

So I think from our perspective, this is a good time for input, sort of ahead of the curve. And we hope that we can make a contribution here, if nothing else just to get our voice heard as one more of what we think is important there.

Some of the things that have occurred, and Cindy has been very diligent in talking to groups such as the Ag Biotech Forum and other groups, to let us know what your thinking is, what you have been doing, what impacts the industry. And this occurred several times last year. You had some announcements about the 2003 plantings that you gave to us, some announcements about plant-made pharmaceuticals and plant-made industrial chemicals being treated in a similar manner. The permit process,

compliance, and enforcement initiatives came out last year. Those all have been to our liking, I can say.

For the most part we've been very supportive of those initiatives and the details within them. We were hoping that these initiatives would eventually fold into ANPR or some ruling that takes some of these guidelines and moves them into regulation. I think that's probably what you were planning.

But just to reiterate that, what we're talking about today here, as well as those, you know, can fold into some regulations which we think would give some good oversight, in a continually-developing technology that needs some adjustments and corrections as it goes along.

Our plan and the comments that we'll make in our formal written comments -- I'll make a lot of comments today probably, and get some feedback from you, which, like yourselves, may be sort of formative thinking that may not end up in the comments that were written, because I have to get approval from all our members as to what exactly we're going to say. So I've been jogging around the country a little bit, and --, as probably you may be doing with us, too.

So the plan really here, what we'd like to see -- and I mentioned that protecting the food supply is one of our primary goals here, as well as letting the technology go

forward -- is really to look at the construction of some of these firewalls that are built through regulation, and to ensure that we feel we're comfortable with it, that these are adequate in achieving our goal.

So we'll be looking at that. And sometimes we think that not just one firewall may be important, but there may be redundancy necessary because of the nature of the biological system. And as John mentioned earlier, we, too, because of our background as food processors, have maintained a science-based approach to all we do. We have laboratories. We have Ph.D.s on staff. We're kind of unique that way. So we are different, and can maintain, through the association of our own resources, an understanding of the science. And so perhaps, then, some of the other groups.

So when we say science-based, that may be not just rhetoric, but something a little bit more concrete than maybe what others have said.

But in thinking about all these regulations that we're talking about, and future regulations, what we'd like to see is an approach to developing regulations that is performance-based. In other words, we're looking for achieving a goal; we're not looking for an prescriptive type of statement. Because we know -- and there's a couple reasons why we want to go with performance-based versus

prescriptive.

We know that science is changing. And when we look at especially some of the developments that are occurring in containment for plant-made pharmaceuticals, the technology is just getting started. There are going to be, I'm sure, some very unique containment systems that are constructed -- not physical systems, but biological containment systems -- that help us get closer to that 100-percent containment goal that we all would like to see.

So that's one of the main reasons that we try and set a goal, set performance standards, and have the regulations meet it, the technology meet it, everybody meets that goal, rather than saying, for instance, you know, you can't grow PMP corn in Iowa or something like that. That, to me, would be very prescriptive. But maybe in a couple years technology would allow you to do that. So that's why we're sticking with trying to formulate regulations and firewalls and whatever we need to ensure the safety of the food supply with some standards that can aim towards that goal.

That really kind of rolls up some of the initial comments that I would make. I'd like to kind of get into some questions that I have, some clarification or dialogue. I've talked long enough, I'm getting dry here.

So let me open it up with sort of a question for

clarification. And perhaps John or Dr. Wach could fill us in a little bit on the environmental impact statement that's going to be developed, a little bit about the mechanics of it. Who is going to be doing it? Maybe it's going to be your group. What the timing is. We know that the National Academy just came out with a report on containment, and maybe that has a lot of the information already in it that we could be using, is that going to be folded into it.

And then once we've talked about the mechanics, maybe we could address how it's going to be used. I have an idea what the purpose of it is after it's done, referring to the exercise that's going to be done, but how it's going to help in the effort of --

MR. TURNER: In terms of who is going to do it, I refer to myself and Michael Wach mentioned by name. But it's going to be, it's a huge effort. And it will involve a large portion of the resources of BRS. Not all the people all of the time, but we'll be forming different teams to work on different parts of this environmental impact statement.

Right now, in terms of time frames, we would like to have a draft finished by sometime next fall. That's a very aggressive time frame, but we're going to attempt to do that.

In the EIS, you mentioned a recent National

Academy report, there are really three which we've paid a great deal of interest to, the one on bioconfinement just being the more recent. But some of the others speaking directly to the way in which we regulate, and our current regulatory system, and things they think we should consider. So we'll be considering the three reports from the National Academies.

Things that we know internally, based on now what's, I guess, over 15 years of experience in regulating these, we have a lot of ideas of improvements. And then stakeholders such as yourself and the others are another major source.

So using all that input, we're going to write a draft EIS. It's a good point to point out that this is the early stage for comment, but there will be other times for comments when the draft environmental impact statement comes out. There will be a comment period in there. And at some point that we have a proposed rule, there will be another comment period. So as we get more and more specific, we can get more comment on what we're doing.

But the idea is that the EIS, first we will list all of the issues that we're considering, things that we think should be prominent in the new rule. And then you'll explore various actions that you could take, that address those issues.

And the idea is if you do a very thorough EIS, then the rule will sort of fall out of the EIS, because it will lead you to certain conclusions. So we'll have the EIS first, and then at some point after that, a proposed rule, and then a final rule.

MR. BARACH: So the events that I mentioned that took place last year, which Cindy participated in and got information and made some proposals, as well as this, will roll into a proposed rule when the EIS is done. So that kind of defines the timing, I guess, for these regulations to go through the process.

But we're really looking at a draft next fall, and then sometime after that for proposed rules, and then a final rule to follow. So this is going to be a process that's going to take some time.

MS. SMITH: That's right. But this is a really significant undertaking that we're doing. We want to make sure we give it the attention it needs in order to really make sure that we're developing the right kind of quality decision-making tools that we need to.

Another thing that I would add in terms of the EIS, in addition to tapping probably just about everyone here in BRS for some input into the rule, we also are looking at the possibility of contract amount, certain scientific pieces of it. Particularly, for example, certain

scientific questions, maybe to a scientific society or something like that. So we are keeping our options open since there's so much work to be done.

MR. BARACH: It sounds like a pretty big undertaking. I would expect there would be parts that perhaps would have to go outside. Okay.

To move on to another area that I am interested in getting a little more definition, is the concept of noxious weed, and how that interplays with the current description of GM crops and plant-made pharmaceuticals.

I wasn't quite clear whether by incorporating noxious weeds and other biological control agents in the scope, we're talking about the scope now, that what you were doing then, or what you would be doing, would be bringing in plant-made pharmaceuticals as noxious weeds, and classifying it that way? Is that --

MS. SMITH: Let me clarify that. What we're not doing is categorizing plants as noxious weeds. What we're doing is we're leveraging the noxious weed authority, which has a very broad definition that essentially, the definition of noxious weed authority is essentially any plant part that could cause harm to food, people, transportation, navigation, all that.

And so what we're doing by leveraging that authority is saying we want to look at genetically

engineered plants to make sure that they don't pose that type of a risk. And so what the noxious weed authority really does for us, we forgot categorizing these plants as such unless we did an evaluation, and the evaluation came to the conclusion that the particular trait in that crop does pose that kind of a threat.

But what it's allowing us to do is just to get to do a very thorough evaluation, looking at much broader areas in our analysis than we currently do under the Plant Protection Act, where we're only looking at plant health.

So under the noxious weed authority, it will allow us to look at, for every crop and trait that comes through the door, it will allow us to look at the food safety impact, the impacts to people, impacts to the environment, navigation. To a number of things that are --

MR. BARACH: And so do you think some will be classified as noxious weeds?

MS. SMITH: It's hard to know. I mean, certainly if they were to meet the definition, then that would be the intent.

MR. BARACH: A plant that produced protein that was a toxin, say for instance human toxin, that's not too far-thinking, because some of the protein toxins could be effective in pharmaceutical applications, where, you know, they can kill cancer cells. Yet they would be very

hazardous. Something like that perhaps, could we classify it as a noxious weed?

MS. SMITH: The idea is for us to have a process to evaluate what's coming to us for regulation against that definition. So that's part of what we are putting together in this process, is what that evaluation will look like.

MR. BARACH: But you're thinking perhaps they would be more of a rare event than a common event. In other words, just because it's a plant-made pharmaceutical doesn't mean that it's going to be a noxious weed.

MS. SMITH: That's correct. I think based on what we see out there right now, we wouldn't envision a lot. But we'll have to see what comes through the door.

MR. BARACH: One of the things that we're interested in, of course, is trade issues. We probably hit on that a couple of times.

The production of regular GM crops has evolved from corn, soy, and cotton, as you know. The next crop that may be out there or coming out there would be genetically-modified wheat.

Up to this point, the group, your sister group, GIPSA, has incurred, through what's called the letterhead statement, that there is no production of genetically-modified wheat in the United States. There are field trials and things like that, but there is no commercial production,

which has been very helpful from a trade issue.

One thing that may be helpful in the future is to apply this type of a certification to plant-made pharmaceutical applications. In other words, maybe -- and we would say today that there are no PMPs produced in corn, for instance -- maybe we can get a little feedback on that aspect, as to whether that type of thing would be possible.

I'm not hearing that everybody is asking for it, but I think once someone commercializes a plant-made pharmaceutical or industrial chemical in food crop, if that does occur, then our trading partners may want some sort of verification, you know, up to that point, that it's not being produced.

Now, after it is produced, and under what conditions, maybe there are different types of letterhead statements that can be made. But it all kind of revolves around the trade issue, and what USDA can do to support the understanding by our trading partners that we haven't had a lot of this.

So I just kind of throw that out on the table as something to think about, because -- some of these definitions and such.

MS. SMITH: That's an interesting, I think, a more novel idea.

MR. BARACH: Oh, you haven't heard that? But, you

know, I work with some of our members who sell growth products throughout the countries, and these letterhead statements are very important to them. I had one just the other day, a member asking for a letterhead statement if there was a new genetically-modified asparagus being produced in the United States. And this was very important to him to sell product into Korea.

So we are interested in these types of things to help move product along.

MS. SMITH: Well, that's interesting. Yes, that's the first time we've heard that. And certainly it will not be our intention, as we update our regulations, to move to regulating on the basis of economics or trade. Of course, it will still be based on risk and science, but that's an interesting suggestion for something that's not really a regulatory consideration, but perhaps something that would be --

MR. BARACH: But it's an authoritative statement coming out of a governmental body that says this is the way it is today. Because as you can imagine, dealing with trade issues, there is a lot of information that flows that is not correct.

MS. SMITH: Right. Okay, thank you.

MR. BARACH: I don't know if the internet helps that, either.

MS. SMITH: Right.

MR. BARACH: One thing that I had mentioned in an earlier set of comments, Cindy, that I still have some question about. When we talked about -- this came up with the issue of plant-made pharmaceutical, plant-made industrial chemicals -- there was a class of compounds that I was interested to know kind of where they fell. And this was the dietary supplements. Things like Ephedra, whatever. If it's produced in a plant, and it's not the traditional plant. Would that be considered a class A industrial chemical? Or would it be a pharmaceutical? Or is it something that, you know, would fall in the cracks, that maybe we need to be sure that it's covered somewhere?

I haven't got any first-hand experience if anybody's doing that, but I can envision that, because of the popularity of dietary supplements, to have some way to work things, or when we define, you know, what is covered, what is a plant-made industrial chemical. So that will probably be something that is in some of our comments.

MR. HOFFMAN: Would something like vitamin-E enhanced plants that are already out there, would that fall into this category? Or are you talking about something that might have a little bit of a stronger biological activity?

MR. BARACH: Something with a stronger biological activity. I think that we, the industry already has

developed some corn plants with different oil, or soy plants with different oil compositions, or enhanced oil compositions. Those kinds of things I think we're comfortable with. The dietary supplements that are biologically active.

MR. HOFFMAN: So maybe in the category that somebody has referred to as botanicals.

MR. BARACH: Right.

MS. KOEHLER: Ephedra or something like that.

MR. BARACH: Yes, where does it fall. We just want to cover it somewhere. So it hopefully would get a permit to leave it in the system.

Let's talk a little bit about the tiers approach, multi-tier approach. Does this mean that the notification process goes away entirely?

MS. SMITH: That's correct.

MR. BARACH: And everything starts out sort of in a tiered process based on risk?

MS. SMITH: Yes, that's right. What we are talking about is replacing, essentially, notification and permitting, with simply permitting. So depending upon the level of risk, it would receive a different permit.

MR. BARACH: This is probably a little out of order, because I think I'm going to come back to the deregulation a little bit later. But I had a note here to

myself to ask about plant-made pharmaceuticals, plant-made industrial chemicals. Would there be a condition where they would become deregulated?

I could, at least I thought that plant-made pharmaceuticals, they would never be regulated, and maybe plant-made industrial chemicals would be at some time. Is that kind of where you're --

MS. SMITH: What you would see, I think, under the new regulations is that we would propose that if pharmaceutical and industrial crops can meet the same safety criteria as needed to in order to be deregulated, then they could be deregulated. It would be a question of whether they can meet that safety criteria or not.government

MR. BARACH: Did you say both? I'm sorry, both?

MS. SMITH: Yes. If they could meet the safety criteria. And then I think you see in the questions, I think in our number six we are referring to our thinking must expand on that a little bit.

MR. BARACH: That's good, because that was my next one.

MS. SMITH: What we're thinking there is that probably many of the pharmaceutical and industrials will not be deregulated, but instead will be maintained under regulation.

And so we're looking at if there is a unique

mechanism that we need to establish to facilitate that specific type of regulation, where it's essentially a field test that's going to be conducted on a long-term basis, the same research or field tests will be run year after year when something is going to commercialization. Is there some better mechanism for us to regulate essentially the commercialization of pharmaceutical and industrial products while they are still under our oversight?

MR. BARACH: Okay. That wouldn't be any different than PMPs, for instance. Because when they are commercialized, you're still going to have strong oversight over it. They will always be under permit.

MS. SMITH: Well, I think what you're going to be seeing in the new regulation is the option, if PMPs and PMIs can meet the safety criteria associated with the deregulation, they could come out from under regulation if they can meet that safety criteria. In other words, if they pose no environmental or food safety or other types of risks.

Alternatively, we're looking at having a different mechanism under the assumption that many PMPs and PMIs will actually go to commercialization still under government regulation. We're looking for a different mechanism in order to enable us to do that.

For example, instead of a company coming to us

every year requesting a permit to do a field test, we do a full review of that. We issue a permit, and then they come back next year with the exact same request. They gathered all the information again, they submit the package again. We do another review. And we have to do that every year, let's say, if they're going to be in commercial production for five years.

What we're looking at is, is there some kind of a mechanism we can use to make that more efficient? Where they develop a long-term plan, and they share the long-term plan with us? And perhaps every year they're providing us additional information, information either that becomes new and is available because of the science, or that they learned as a result of the previous year's crop, an analysis of that crop and data gathered through that.

Another thing we're looking at is how we can make commercialization of pharmaceuticals and industrials, while under government regulation, more transparent. Because we think it's really important for the public to have a sense of confidence in what it is that's being field tested, and the safeguards that are in place for that field testing. So we're also looking for how we can provide more information to the public. Honor confidential business information, but have a mechanism that is more open to the public in terms of communicating what's being field tested, and why it's safe

to be field tested in the way that we approved it to be tested.

MS. BECH: A point of clarification. It would have to meet more than just USDA safety. We're talking about considering FDA's approvals and things like that, as well.

MR. BARACH: I want to talk a little bit about that. But okay, that is helpful, because I wasn't clear when you described in number six, what a new mechanism is, exactly what you were referring to there.

MS. SMITH: And that's something that there is a lot of room to develop what that looks like. We don't have something very clearly in mind. We have some ideas, but that's the kind of thing that we're looking for comments on.

MR. BARACH: I don't know how much help we would be there, because you know, not having experience with the permitting process or knowing what the steps are.

MS. SMITH: Well, the way that you can be helpful is just in making sure that we are aware of what your concerns are. And then we could make sure we're addressing those concerns in the process that we develop.

MR. TURNER: The idea is not necessarily to give lighter regulation, but to have a more efficient process. It's going to a different stage, to focus on what's important in terms of routine production.

MR. BARACH: In the write-up that you talk about, adventitious presence, and I know that we had some discussions at different forums about that, that is a very important concept to us, because it is a little bit of a relief valve. We know that biological systems aren't going to be 100-percent pure in all cases.

But I wanted to point out that I think it has at least three components that are important. One is the one that you are looking at, for adventitious presence in the field trials, that there's something that happens there, or even in commercialization. But that's probably the point that you have the most focus on.

But in addition to that, there is the concept for adventitious presence in regard to what the FDA regulations are. Here we're talking about a situation where adventitious presence may be allowed or may be permitted in a field trial, but yet when it enters into the system, it takes on a different light from an FDA standpoint. In other words, the food or the food material becomes adulterated.

So that's another aspect of AP that we want to work on.

And the third is the international aspect, the trade aspects. I know you're not going to deal directly with that, but that's okay. But just to keep it on the, you know, on the horizon as far as thinking about if we solved

an AP problem, if we make a regulation or if we have a way to fix it, we need to think about all three of those components, so that the fix meets the need, which is our need on at least those three, and maybe other ones.

I just wanted to bring that up. I think going down the road towards that AP tolerances, the way we handle it, the way we describe it is right-on. I'm not discouraging that. I'm just saying, you know, that let's think about these other things that are on the, you know, that some of the other groups have to worry about when we make a fix.

MS. SMITH: We appreciate you pointing it out. And that's actually a pretty good paradigm for most of what we're considering, is any changes that we consider, making sure they're complementary to what's happening with the other agencies, as well as the impacts, the international considerations.

MR. BARACH: This particular one, though, it really juts out.

MS. SMITH: It really does.

MR. BARACH: Because it has special needs all the way through.

Another area that I think is important is what we perceive as being one of the most difficult aspects -- and I'm getting back to plant-made pharmaceuticals -- of how

these things are going to be --

We know the regulations are going to be there. We know that the intent of the companies are going to be the best. But it's the human error that we worry about the most. And there doesn't seem to be a real good fix on that.

But we have some suggestions. And one thing we'd like to see, and we like it so far as what we've seen, is the concept of HACCP. And I think we've been introduced to it probably not really in a lot of depth yet, because it is something that is really something new.

For those of you who may not know what it is, I'll back up a little bit. The food system, production of food has had what's called HACCP, hazard analysis critical control point, programs for many years, dating all the way back to the 1960s. These have more currently been regulated by both the FDA and USDA for meat, poultry, on the USDA standpoint, for seafood and for juice from the FDA standpoint.

So we are familiar with HACCP, analyzing the hazards, developing the firewalls or the solutions, so that the hazard doesn't occur in food, and that the food that's produced is safe. There's lots of material on that. And if you look on even the FDA's website, and perhaps the USDA's, you'll find out more about what HACCP is.

HACCP is the parallel approach for containment.

And we've worked with several of the other credit groups and individual companies to take the principles of HACCP, and to move them into the containment area, so that the containment hazards are identified, and that they're mitigated in their approaches.

We see that this is valuable, and puts a systematic approach to addressing these issues, some of the issues that we've had. And it also fits into our description of letting people choose whatever containment systems they have, and not prescribing something, but letting the performance be whatever it's set at. So that you can meet that using a systematic approach and a scientific approach.

We'd certainly like to see that the industry, and for all levels of the industry, be they the big companies, the smaller biotech companies, or even the universities, which we worry about, too, could develop some sort of approach using this systematic analysis. We'd like to see that tied in maybe to the permitting process, and then institutionalized, and then maybe even regulated. Always lay it on the table. I think that's the way it worked well for the food industry. I can see that that may work very well for this group. It wouldn't happen overnight, but certainly it's an approach to developing some systems that have real value and gain a lot of the goals that we're all

interested in.

Certainly I would volunteer to work with anybody, you know, to describe more about what goes on in the food system. And some of the other folks can talk a little bit about what they developed as far as the plant-made pharmaceutical containment.

Another thing that we are concerned about, as I mentioned at the outset, we're one of the stakeholders. We have a lot of perceived risk in some of these things, and not a lot of reward. So one thing that pops out to us and the question that often comes up is, well, who assumes the liability of these issues as somebody develops and puts a new pharmaceutical or a new GM crop out on the market? Where does the liability fall?

Unfortunately, we've had in our experiences with Starlink -- I know it's not exactly the same, but the food industry has had to go through some generations in giving product back and handling products. So liability is an issue.

In trying to think about what USDA has in resources already, so we don't have to invent something totally new, I don't know enough about these groups of know whether there's any interplay or discussion or whatever. But two groups kind of pop out when you think about liability. The Commodity Credit Corporation helped the

Starlink situation. And you've got another group, Federal Crop Insurance Corporation, that deals with the farmers and their issues of crop production.

I don't know whether there's any discussion that's even reasonable between, you know, your group and these groups to talk about the issues of liability. But just to put it on the table is something we're concerned about. How do we make sure that the companies that are going down these roads to development have the resources to back up any mishap that occurs? Do you make them take out a bond or something? Or do you make them get a huge amount of liability insurance, or whatever, I don't know.

Some of the companies are pretty small, and they are running fast and furious on venture capital. They don't have a lot of resources. Bigger companies, I think, I don't worry too much about them having the resources to handle it. But that's just an issue, and we don't really address this issue. Maybe this is not the best forum. But I know the USDA has dealt with this, and has these other groups. So perhaps a discussion to find out what's going on would be valuable. And to talk about our liability with some of these other groups, if that would be appropriate, we would be glad to talk about that.

Perhaps the last topic that I wanted to cover was one that involves more of an interaction between the

agencies that we've been working on, and -- about ready.

The FDA came out with a premarket biotech replication proposed rule back in, I think it was January of 2001. And what the proposal there was was twofold. One was to get information out to the public, to be more transparent about what was going to be commercialized. But the other one was to give confidence that there is somebody actually looking at these developments before they come out on the market.

We first talked to FDA, and that process seems to be stalled, for various reasons. We're interested in fixing that, if possible, because we still think there's a transparency need, and we still think that the commercialization of crops -- we're talking about regular genetically-modified crops -- ought to be put out there ahead of time, before the crops are actually commercialized.

There is, in your deregulation process, there is an element which addresses something similar. And this is the element number seven, adverse consequences of an introduction of a new cultivar.

One of the criteria is that there is no known reported toxic properties. So for someone to get a deregulated product, they must meet the certain criteria that you have.

Now, I don't know, I'm not that familiar with how

that traditionally has been approached. But I'm thinking that that may have some relevance to what we're thinking about, where there is no known reported toxic properties. If you were to confirm that with the FDA, there would be a good interplay between agencies. And before the deregulation process started.

Now, I know it's not always the most popular topic to have agencies necessarily layered or relying on each other too much, because the process gets slowed down. But in this case it may be appropriate, before deregulation occurs, to work with another agency that is addressing, as it seems, that there's no known reported toxic properties as one of your criteria, to get a confirmation. So that this information, before the product is commercialized --

I just lay that on the table. I think that that's probably an area we ought to work more with you on, one on one. But that's one way to do it. There's probably a lot of other ways, but just thinking about that.

We think that that's an admirable goal, to get to a point where we can notify the public. And it fits well in our goals for transparency, and also it sounds like with your goals, too.

That pretty much exhausts my list. And as I said, our comments, our written comments will reflect --, in addition to our membership. So they may come out slightly

different than this. We don't always reach consensus on all things, but they don't tend to be too far off. And that will be the written record of what statements we make.

MS. SMITH: Okay, well, thank you. Can we take a couple minutes to see if we have any questions we want to ask?

MR. BARACH: Sure.

MR. WACH: Actually, I have a question.

MS. SMITH: Yes? Go ahead.

MR. WACH: This is Mike Wach speaking. One of the things we're really hoping for in this process is for the EIS not only to address where we are now, but we want it to be a forward-thinking document. We want the rules to be forward-thinking, sa well.

And one of the trends that we see, in terms of genetic modifications that are proposed, are those that would either enhance nutritional quality or enhance food processing parameters.

And I wanted to ask you, as a representative of your organization, how do you feel about those? Do you feel that those need the same kind of care that a PMP would? The same kind of oversight that you would look for in terms of adventitious presence? And also, how do you feel that the perception is moving on those sorts of trades, as opposed to pharmaceuticals and industrials?

MR. BARACH: That's a good question. And it fits well within some of our discussions that we've had internally about what the benefits of biotech are for the food industry.

And we have talked to our membership about those types of developments in nutrition. Do they want events or developments that allow processing to occur under less energy or less waste, or whatever? You know, all those are interesting concepts.

Probably the limit comes out that rises to the top, is the concept of something health-related as being the most interesting to consumers, and also to our food company members. So some concept that makes food healthier, whatever that is, is something that probably will be some of the first things to come out, and hopefully some of the things that are most attractive to food processors.

As far as the way that they would be regulated, I think you almost have to look at them on a case-by-case basis. Look at vitamin A. Vitamin A, at very, very high levels, can be toxic. So I'd have a problem there if that were to occur. But yet, you know, if it's just enhanced two or three times or something to the level that's in a vitamin tablet, you know, maybe not.

So it's almost a case-by-case basis, I think. And that's how, to the extent you are looking at a lot of these,

and your new structure seems to allow that to occur by looking at the risk, by associating each of those.

MS. KOEHLER: If I might follow up on that. I know there are at least two research groups that are looking at reduced allergens, one in rice and the other one in soybeans. I mean, that would be something with obvious health benefits, but for which you would need just as much segregation to keep that product pure if you're going to reap the benefits of it, as you would for a pharmaceutical.

Has there been any discussion at all in the food industry for those kinds of products?

MR. BARACH: Definitely. Also for wheat, with celiac disease. You know, that is another area that, as well as the ones you mentioned, where there could be a product which is a high-value product, and it's going to be more expensive because you're going to have to use identity preservation-type systems. You're going to add a certain amount of cost to it to segregate it to contain it, to certify that it is what it is, to test it.

But yet there may be a market for those types of products, just like there would be for organic or others. So I think that yes, those health-related-type products, reduced-allergy products, would be valuable. And could be segregated, could fit within the system. And should not be difficult to regulate under the current system.

MS. SMITH: Questions? Okay, then, thank you. We really appreciate you coming in. We appreciate your comments, and look forward to talking to you in the coming months, as well.

MR. BARACH: Thank you very much. I appreciate all of your efforts.

MS. SMITH: Thank you.

(Whereupon, at 2:38 p.m., the meeting in the above-entitled matter was adjourned.)

//

//

//

//

//

//

//

//

//

//

//

//

//

REPORTER'S CERTIFICATE

CASE TITLE: NATIONAL FOOD PROCESSORS ASSOCIATION
HEARING DATE: February 25, 2004
LOCATION: College Park, Maryland

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Department of Agriculture.

Date: February 25, 2004

Renee Miskell
Official Reporter
Heritage Reporting Corporation
Suite 600
1220 L Street, N. W.
Washington, D. C. 20005-4018